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**IN THE UNITED STATES DISTRICT COURT**
**THE DISTRICT OF NEW JERSEY**

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| ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, | : | |
| v. | : | Civil Action No. 11-760 (JAP)(TJB) |
| HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs. | : | |

**Hanmi's Motion *in Limine* No. 2**
**(To Preclude New Case Theories Never Disclosed In AstraZeneca's Contentions)**

Pursuant to Local Patent Rules 3.6 and 3.7 and Rule 37(c)(1) of the Federal Rules of Civil Procedure, Defendants Hamni USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. (collectively "Hanmi"), respectfully submit this Motion *in Limine*, to strike and preclude AstraZeneca's new and untimely theories of its case, introduced for the first time in the opening expert reports of Drs. Davies, Byrn, Johnson, and Levy, dated February 19, 2013, and the report of Dr. Bartlett, dated March 25, 2013, and exacerbated in subsequent reports. AstraZeneca should be precluded from presenting testimony and evidence as to theories and contentions which are beyond the scope of AstraZeneca's contentions, as both untimely and prejudicial.

## I. ASTRAZENECA'S EXPERT REPORTS IMPROPERLY CONTAINED NEW THEORIES NOT PREVIOUSLY DISCLOSED IN ITS CONTENTIONS

### A. Expansion of Doctrine of Equivalents

#### *1. AstraZeneca's Narrow Contentions Under The Doctrine of Equivalents*

The Local Patent Rules of this District use a carefully crafted framework in Hatch-Waxman cases. *See e.g.* L. Pat. R. 3.6 and 3.7. A patentee's disclosure of asserted claims limits the scope of the case in a broad sense, and the parties' subsequent infringement and invalidity contentions limit the scope of the case in terms of their theories of the case. This approach not only is logical from a legal standpoint, but fair from a case management standpoint.

This case has been pending since February of 2011. AstraZeneca has had a full description of Hanmi's Proposed NDA Products since April of 2011. *See* D.I. 86-3, Letter from Hanmi to AstraZeneca, dated April 1, 2011. On May 25, 2011, Hanmi served its initial non-infringement and invalidity contentions setting forth its basis of no infringement under the doctrine of equivalents.[1] (*See* D.I. 87-1, Hanmi's Initial Non-infringement Contentions, dated

[1] Hanmi was permitted to amend its contentions to respond to Plaintiffs' late assertion of claims 3, 5 and 10 of the '504 patent (D.I. 145) in this case and also properly moved the Court (L.Pat. R. 3.6, 3.7, D.I. 238) for, and was granted leave to amend its contentions a second time for the purpose of conforming its contentions to the summary judgment record (D.I. 269).

May 25, 2011, at pages 14-21). Hanmi subsequently amended its non-infringement contentions, after AstraZeneca was permitted to add dependent claims 3, 5 and 10 of the '504 patent, which claim specific salts other than Hanmi's strontium salt. *See* D.I. 179-10, Hanmi's First Amended Non-infringement and invalidity contentions, dated December 9, 2011, pp. 14, 18-25. Thus, despite the now-resolved dispute over the scope of "alkaline salt" in the '504 patent claims and "pharmaceutically acceptable salt"[2] in all of the asserted '192 patent claims, doctrine of equivalents due to different salts has been an issue in the case since 2011, based at least on claims 3, 5 and 10.[3]

From its first contentions, AstraZenenca's theory of infringement under the doctrine of equivalents with respect to the '504 patent was based on a single box in a chart in an Attachment to its infringement contentions:

> If not literally present, Hanmi's product will infringe under the doctrine of equivalents because the strontium salt of esomeprazole is equivalent to alkaline salts of esomeprazole (*see, e.g.,* at least HAN0000228-337).
>
> Hanmi represented to FDA that strontium salts of esomeprazole are equivalent to other alkaline salts, "It is known in the public domain that natural strontium, which belongs to the same alkali earth metal as magnesium or calcium in the periodic table, is a safe element and its pharmacological activity is similar to calcium." (*See, e.g.,* HAN0000244). Hanmi also represented to FDA, "the pharmacological activity of esomeprazole sodium or magnesium salts is well documented. It is therefore presumed that the pharmacology of esomeprazole strontium should be the same as for esomeprazole sodium or magnesium salt." (*See, e.g.,* HAN0000255). Hanmi made additional statements to FDA equating strontium to calcium: "Strontium is known as a molecular surrogate for calcium in the body," "The distribution of strontium absorbed into the body is similar to that of calcium," and "The metabolism of strontium is similar to calcium." *(See, e.g.,* HAN0000287-288). And Hanmi states, "Strontium is an alkaline earth element of Group IIA, like Mg and Ca." (*See, e.g.,* HAN0000443).

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[2] *See* D.I. 257, Claim Construction Opinion dated December 10, 2012.

[3] Based on the Court's claim construction opinion (D.I. 257) construing the terms "alkaline salt" and "pharmaceutically acceptable salt" as "$Na^+$, $Mg^{2+}$, $Li^+$, $K^+$, $Ca^{2+}$, or $N^+(R)_4$" and the Court's denial of AstraZeneca's Motion for Reconsideration of the construction of claim terms (*see* D.I. 282, dated March 25, 2013), there is no issue of literal infringement framed for trial. AstraZeneca is precluded from presenting arguments, testimony or evidence relating to literal infringement at trial.

(*See* Ex. 31, AstraZeneca's Amended Infringement Contentions, dated March 19, 2012, page 2 of Attachment A). AstraZeneca also referred to its opposition to Hanmi's summary judgment motion no. 1 and supporting evidence (*id.*), which, as discussed below, was directed to different issues. AstraZeneca's position was the same for the "alkaline salt" claims of '504 patent as for the dependent claims reciting specific salts (*id.,* at pages 6-8 and 12-13). For the "pharmaceutically acceptable salt" of the '192 patent claims, AstraZeneca's position was the same as for "alkaline salt" of the '504 claims. *See* Ex. 31, AstraZeneca's Amended Infringement Contentions, dated March 19, 2012, Attachment B, pages 3-4.

Thus, throughout the case and up to opening reports served February 19, 2013, AstraZeneca elected to assert a doctrine of equivalents theory based ***solely*** on statements in Hanmi's NDA concerning the ***bioequivalence/pharmacological activity*** of its esomeprazole strontium salt. *Id.* at Attachment A, pp. 2, 4-8 and 13.

**2. AstraZeneca's New Doctrine of Equivalents Theories**

Hanmi respectfully requests that the following new theories under the doctrine of equivalents, present in AstraZeneca's expert reports but not in its contentions, be barred from presentation at trial:

1) **"Function/Way/Result":** Any allegations or evidence that Hanmi's esomeprazole strontium tetrahydrate satisfies any aspect of the "function / way / result" test under doctrine of equivalents precedent in comparison to the claimed salts. AstraZeneca's contentions made no reference to "function / way / result" in its contentions, much less attempted to explain evidence that purports to meet the relevant standards, yet its expert reports are replete with such theories and analyses (*see e.g.,* Ex.2, Expert Report of Stephen G. Davies ("Davies Opening Report") at ¶¶20, 36; Ex.10, Reply Report of Stephen G. Davies ("Davies Reply Report") at ¶¶11, 94; Ex.4, Expert Report of David A. Johnson ("Johnson Opening Report"), at ¶¶18, 38; Ex.12, Reply Report of David A Johnson ("Johnson Reply Report") at ¶18; Ex.5, Expert Report of Rene H. Levy ("Levy Opening Report") at ¶¶ 21, 36, 153-157; Ex.9, Reply Report of Rene H. Levy ("Levy Reply Report") at ¶ 8; Ex.3, Expert Report of Stephen R. Byrn ("Bryn Opening Report") at ¶¶19, 40).

2) **"Insubstantial Differences"**: Any allegations or evidence purporting to show that Hanmi's esomeprazole strontium tetrahydrate is not "substantially different" from the claimed salts. AstraZeneca's contentions made no reference to "insubstantial

differences" in its contentions, much less attempted to explain evidence that purports to meet the relevant standards, yet its expert reports are replete with such theories and analyses (*see e.g.,* Ex. 2, Davies Opening Report at ¶¶20, 27, 36, 90-95; Ex. 10, Davies Reply Report at ¶¶ 4, 11, 57, 84-87, 94; Ex. 4, Johnson Opening Report at ¶¶ 18, 28, 38, 96-98; Ex. 12, Johnson Reply Report at ¶ 19; Ex. 5, Levy Opening Report at¶¶ 21, 28, 36, 153-157; Ex. 9, Levy Reply report at ¶ 7; Ex. 3, Bryn Opening Report at¶¶19, 29, 40, 122; Ex. 11, Bryn Reply Report ¶90).

3) **Equivalence based on crystalline and solid state properties:** Any allegations or evidence purporting to show that Hanmi's esomeprazole strontium tetrahydrate is "equivalent" to the claimed salts based on crystalline and solid state properties, because such theories are not in AstraZeneca's contentions. Specific examples of the new theories include:

   - Hanmi's esomeprazole strontium offers the same "solid state" advantages over the prior art syrups as do the claimed salts, *e.g.*, $Mg^{2+}$ and $Na^{+}$ (and is equivalent for that reason). *See e.g.,* Ex. 3 Byrn Opening Report at ¶¶ 119-122.
   - The crystalline nature of Hanmi's esomeprazole strontium provides the same advantage over the prior art with respect to the ability to purify salts as do the claimed salts, *e.g.*, Mg and Na, and more broadly that Hanmi's API exhibits the same properties that distinguish the alkaline salts of the '504 and '192 patent inventions from the prior art. *See e.g.,* Ex. 3, Byrn Opening Report, ¶¶ 119-122; Ex. 2, Davies Opening Report at ¶¶ 94.
   - Hanmi's strontium salt is of sufficient optical stability and crystallinity to permit further optical purification to greater than 94% e.e., 98% e.e., and 99.8% e.e. *See e.g.,* Ex. 2, Davies Opening Report, ¶¶ 35, 86-89, 93.

4) **Equivalence based on route of synthesis:** Any allegations or evidence purporting to show that Hanmi's esomeprazole strontium tetrahydrate is "equivalent" to the claimed salts based on route of synthesis process comparisons, because such a theory is not in AstraZeneca's contentions. Specifically, this new theory includes arguments that Hanmi's strontium salt can be prepared from the neutral form of esomeprazole with strontium hydroxide base, which is alleged to be similar to a method shown in the '504 patent for the production of the claimed salts. *See e.g*., Ex. 2 Davies Opening Report, ¶ 92; Ex. 10, Davies Reply Report ¶19-35.

5) **Equivalence based on mechanism of action *in vivo*:** Any allegations or evidence purporting to show that Hanmi's esomeprazole strontium tetrahydrate is "equivalent" to the claimed salts based on *in vivo* mechanism of action comparisons, because such a theory is not in AstraZeneca's contentions. Specific examples of this new theory include:

   - The properties of esomeprazole strontium and Nexium, such as solubility, do not affect the rate or extent of absorption into the bloodstream, and thus the difference in solubility has no impact (and is equivalent for that reason). *See* e.g., Ex. 9 Reply Expert Report of Rene H. Levy, PhD. ¶¶7-37 and the references cited therein;
   - Hanmi's strontium salt will dissociate after ingestion and will exhibit the same pharmacodynamics properties (pK, pKa, solubility, dissolution) as the claimed alkaline salts of esomeprazole (and is equivalent for that reason). *See e.g*., Ex. 5

Levy Opening Report, ¶¶31, 34-36, 73-77,153-157, Ex. 7 Johnson Opening Report, ¶¶75-77; Ex. 12, Johnson Reply Report ¶¶18-19.

These new theories were never disclosed in any version of AstraZeneca's infringement contentions, nor did AstraZeneca ever seek to amend its contentions to include any of them. Rather, they are found for the first time in the February 19, 2013 Byrn, Davies, Levy, and Johnson Reports. No justification exists for the belated introduction of AstraZeneca's previously undisclosed theories. Hanmi has had no notice of these theories and no opportunity to defend against them. Injection of multiple new infringement theories at this late stage severely prejudices Hanmi, as any opportunity to pursue relevant fact discovery, to retain additional experts, or for Hanmi to undertake its own testing to rebut conclusory opinions of AstraZeneca's experts has been usurped.

AstraZeneca "submarine" is at odds with the Federal Rules, Local Patent Rules and the Court's Scheduling Order. *See* Fed. R. Civ. P. 37(c)(1), L. Pat. R. 3.6 and 3.7; *King Pharm., Inc., v. Sandoz, Inc.*, Case No. 08-5974 (GEB-DEA), 2010 WL 2670804, at *1 (D.N.J. June 29, 2010). AstraZeneca's new theories should be banned from presentation at trial.

AstraZeneca's contentions cite to Hanmi's NDA, strictly concerning ***bioequivalence*** of Hanmi's strontium esomeprazole salt and "alkaline salts" of esomeprazole, more specifically magnesium trihydrate (Nexium®), and safety comparisons with $Ca^{2+}$. *See* D.I. 31, AstraZeneca's Amended Infringement Contentions, dated March 19, 2012, page 2 of Attachment A. The mere incorporation of AstraZeneca's opposition to Hanmi's summary judgment motion 1 and supporting evidence gives no indication of what, if anything, in the opposition papers goes to establishing that Hanmi's esomeprazole strontium salt satisfies the legal standards under controlling precedent for proof of an equivalent claim element. *See Abbott Labs. v. Sandoz, Inc.,* 566 F.3d 1282, 1298 (Fed. Cir. 2009)(distinguishing bioequivalence from patentable

equivalents.)[4] Hanmi's summary judgment motion 1 had nothing to do with the doctrine of equivalents, with respect its new salt form versus the claimed salts of the '504 and '192 patents, and neither party discussed or briefed the legal standards for proof of infringement under the doctrine, much less theories of infringement under the doctrine. *See* D.I. 98, Memorandum in Support of Hanmi's summary judgment motion 1 and D.I. 146, AstraZeneca's Opposition to Hanmi's summary judgment motion 1. At best, AstraZeneca pointed out certain Hanmi statements from its NDA, made in the context of establishing bioequivalence at the FDA. *See* D.I. 146 AstraZeneca's Opposition to Hanmi's summary judgment motion 1, at p. 6 and footnote 5, citing ¶¶130-166 of D.I. 149 Statement of Facts in Support of AZ's Opposition to Hanmi's SJ Motion 1.

AstraZeneca's contentions, including its opposition to Summary Judgment Motion 1 and supporting evidence, reveal no legal or factual theory recognized under the doctrine of equivalents. AstraZeneca's contentions make no reference to the "substantial differences" analysis set forth by the Supreme Court in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17 (1997), much less show how its asserted evidence meets these factors.[5] AstraZeneca should be precluded at trial from putting on evidence in support of any of these *Warner Jenkinson* factors.

AstraZeneca's contentions make no reference to the "function / way / result" test under the doctrine of equivalents--sanctioned by the Supreme Court in *Warner-Jenkinson, supra,* but

[4] AstraZeneca's opposition to Hanmi's summary judgment motion 1 and supporting evidence are directed to establishing that the biological effects language of claims 1-11, 13-18 and 20-23 of the '192 patent does not require an active comparative step with omeprazole. It does not address doctrine of equivalents issues between Hanmi's strontium salt and the claimed salts. *See* D.I 146, AstraZeneca's Opposition to Hanmi's Summary Judgment Motion 1.

[5] The Supreme Court in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co*., stated that factors to be considered in assessing the substantiality of the differences include: (1) whether persons skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was; (2) evidence of copying; (3) efforts to design around the claims of a patent; and (4) evidence of independent development. *Id.* at 29, 39-41.

characterized as a "poor framework" for non-mechanical inventions (520 U.S. at 39-40), much less explain how any evidence on which it will seek to rely applies to these factors.

Certain statements in AstraZeneca's contentions on doctrine of equivalents compare certain properties of just the cation strontium to the cation calcium *in vivo,* where each has its own activity per se. *See* D.I. 31, AstraZeneca's Amended Infringement Contentions, dated March 19, 2012, page 2 of Attachment A and pages 3-4 of Attachment B. This has no relevance as to whether AstraZeneca can prove "insubstantial differences" between Hanmi's esomeprazole strontium and the claimed esomeprazole salts, and the theory comparing just cation to cation appears to have been abandoned by AstraZeneca, in favor of its new theory relying on the *in vivo* mechanism of action of the dissociated esomeprazole anions.

Putting aside the lack of any legal framework in its contentions, without notice AstraZeneca asserts new theories of equivalence based on physical and structural properties (solid state, crystallinity as it relates to optical purity) of Hanmi's esomeprazole strontium tetrahydrate as compared to the claimed esomeprazole salts. Such theories were not previously disclosed, and should be precluded.

Nor do AstraZeneca's contentions reveal any theory of equivalents based on process or route of synthesis comparisons. This comes as no surprise as the particulars of synthesis and process parameters are simply not the subject of any of the asserted claims (*see* D.I. 21, D.I. 86-2, '504 patent, claims 1-7 and 10; D.I. 111-9, '192 patent, claims 107, 10-19 and 21-23). In any case, this new theory should be precluded.

AstraZeneca's contentions likewise reveal no theory of equivalents based on comparisons of the mechanism of action *in vivo*. Claim 1 of the '504 patent is directed to a pharmaceutical formulation containing a solid state salt of esomeprazole. *In vivo* mechanism of action evidence, focusing on the actions of esomeprazole after it no longer exists in salt form, would improperly vitiate the solid state salt aspect of the alleged "novel salt" for each of the asserted

claims (see e.g., '504 patent at col. 2, ll. 42-49). Under the "all elements rule," the doctrine of equivalents cannot apply if it would result in an entire claim limitation being vitiated. *See Planet Bingo LLC v. GameTech Int'l, Inc*., 472 F.3d 1338, 1344 (Fed. Cir. 2006); *see also Warner-Jenkinson v. Hilton Davis Chemical*, 520 U.S. 17, 29 (1997) ("It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety.").

Here, AstraZeneca's *in vivo*, post-dissociation evidence would effectively eliminate the solid state salt aspect of the asserted claims--the alleged point of novelty over the prior art enantiomers of omeprazole. Under AstraZeneca's new theory of infringement, the claimed invention would operate in the same way, perform the same function, and achieve the same results as the prior art neutral forms of the enantiomer of omeprazole. *See* '504 Patent at col. 1, ll. 27-32. Thus, for the reasons stated above, AstraZeneca's new theories of infringement under the doctrine of equivalence should be precluded at trial.

**B. Expansion of the Literal Scope of the '504 and '192 Patent Claims Related to Hydrates**

AstraZeneca has also improperly expanded its theories regarding the literal scope of the '504 and '192 patent claims as related to hydrated forms of (-)-omeprazole. AstraZeneca has previously asserted that hydrated forms of (-)-omeprazole are not recited in the claims of the '504 patent and therefore, the specification is not required to enable or describe such forms:

> The '504 Patent provides written description support for the *claimed* pure solid state alkaline salts of esomeprazole *as of the filing date.* "Hydrates" is term that is simply not recited in any of the claims in this case. By imposing a written description requirement for hydrates, Hanmi contradicts fundamental patent law principles. The '504 patent also enables one of ordinary skill in the art to make and use the *claimed* pure solid state alkaline salts of esomeprazole *as of the filing date*, without undue experimentation. Hanmi's attempt to focus the enablement inquiry on "hydrates" is in violation of the prohibition on importing limitations into the claims—the claims in the '504 Patent are not limited to "hydrates."

(*See* D.I. 153, page 2, see other AstraZeneca positions, summarized at D.I. 238-1, Hanmi's Memorandum in support of Motion to Amend contentions, pp. 4-6).

Not until Dr. Byrn's Report On Infringement, filed February 19, 2013, did AstraZeneca provide any insight into its theories of how the '504 and '192 patent claims allegedly could cover hydrated forms of (-)-omeprazole salts. Specifically, AstraZeneca now asserts that "solid state," recited in the '504 patent claims, provides the "hook" for the '504 patent to cover hydrated forms of (-)-omeprazole salts. *See* Ex. 3, Byrn Opening Report, ¶¶ 111-113.

In response, Hanmi moves *in limine* to exclude the following new or revamped theories of the literal scope of the '504 and '192 patent claims relating to hydrates:

- A person of ordinary skill in the art would interpret "solid state" alkaline salt to cover alkaline salts of esomeprazole in any solid form -- crystalline or non-crystalline, solvated or non-solvated. *See, e.g.*, Ex. 3, Byrn Opening Report ¶¶ 111-113 and the references cited therein; Ex. 11, Byrn Reply Report ¶¶ 7-12 and the references cited therein;

- It would be impossible to describe all possible solid forms of a compound, so a person of ordinary skill in the art would expect solid (-)-omeprazole might exist in different solid state forms, including hydrates. *See* Ex. 8, Rebuttal Report of Stephen R. Byrn, PhD Concerning Validity, dated March 25, 2013 ¶¶ 39-45 and references cited therein;

- In the absence of an express hydrates limitation in the claims, a person of ordinary skill in the art would have expected that all known forms of (-)-omeprazole salts were hydrates. *See* Ex. 8, Report of Stephen R. Byrn, PhD Concerning Validity, dated March 25, 2013 ¶¶ 48-51; and

These theories as to the scope of the '504 and '192 patents were never disclosed in any version of AstraZeneca's infringement or validity contentions, nor did AstraZeneca ever seek to amend its contentions to include these theories. Rather, AstraZeneca presented these constructions for the first time in the February 19, 2013, March 25, 2013 and April 8, 2013 Reports of Dr. Byrn referenced above. Hanmi had no notice of these theories before expert discovery.

### *C. Expansion of Contributory Infringement*

AstraZeneca has also expanded its contributory infringement case to include a new theory related to Hanmi's formulation of its API product. Hanmi therefore moves *in limine* to exclude the following new contributory infringement theory:

- Because Hanmi twice reformulated its product to more closely match the release profile of Nexium®, Hanmi's product allegedly "was especially adapted or made to be bioequivalent to Nexium®" (a completely new theory relating to 35 U.S.C. § 271 (c)). *See e.g.,* Ex. 3, Report of Stephen R. Byrn on Infringement, dated February 19, 2013, ¶¶ 123-130 and references cited therein.

AstraZeneca's theory of contributory infringement has throughout this case been limited to manufacturing, importing, using, or selling in the US its NDA product (1) with a partner or (2) with knowledge that its NDA product and label is made for an infringing use that is not a staple article suitable for non-infringing use. *See* Ex. 31, AstraZeneca's Amended Infringement Contentions, dated March 19, 2012, pp. 2-3 and Attachment A at e.g., p. 4 (discussing carrier aspects but nothing concerning reformulation or matching any release profile.). Nowhere in it contentions does AstraZeneca refer to Hanmi's "reformulation efforts" as grounds for establishing contributory infringement. Yet, AstraZeneca's primary theory of contributory infringement has now shifted to a previously-undisclosed – and entirely speculative – reformulations-based theory. *See e.g.,* Ex. 3, Byrn Report on Infringement, ¶¶ 123-130. This new theory should be precluded.

**D. Expansion of The Allegedly Relevant State of the Prior Art**

AstraZeneca should be ordered to limit its rebuttal case on obviousness to not exceed a fair scope of its contentions. Hanmi therefore, moves *in limine*, to exclude the following new theories in Drs. Bartlett's and Johnson's reports:

- The state of the art for treatment of gastric acid-related disorders, including histamine $H_2$-receptor antagonists, proton pump inhibitors, neurotransmitter antagonists, gastrin receptor antagonists, cytoprotective agents, and other agents. *See, e.g.,* Ex. 6, Rebuttal Report of Paul A. Bartlett, filed March 25, 2013 at paragraphs 94-113 and exhibits cited therein; Ex. 7, Rebuttal Report of Dr. David A. Johnson, filed March 25, 2013 at paragraphs 34-48, 82-108, and exhibits cited therein.

- A person of ordinary skill in the art would have been aware of the great variety of compounds that demonstrated clinical utility in addressing gastrointestinal disorders or were being investigated for that purpose. *See, e.g.,* Ex. 6 Rebuttal Report of Paul A. Bartlett, filed March 25, 2013 at paragraphs 114-122 and exhibits cited therein.

- Dr. Atwood used hindsight in his analysis under 35 U.S.C. §103(a) in failing to consider a great variety of compounds and the state of the art as of 1993. *See, e.g.,* Ex. 6 Rebuttal

Report of Paul A. Bartlett, filed March 25, 2013 at paragraphs 145-174 and exhibits cited therein.

In its response to Hanmi's contentions that the asserted claims of the '504 and '192 Patents are anticipated by Kohl DE '455 and if not anticipated, any difference (such as optical purity) would have been obvious, AstraZeneca's responses included rebuttal at pages 13-38. *See* Ex. 31, AstraZeneca's Amended Responses to Hanmi's Invalidity Contentions, dated March 19, 2012, pp. 13-38. Among other points, AstraZeneca asserted that one would not have been lead to Kohl's disclosure of (-)-omeprazole (*id.* at pg. 17 *et seq)* and that the relevant prior art included those working in "PPI drug discovery" as of May 1993 (*id.,* at p. 22 *et seq*).

Now, however, AstraZeneca's experts have significantly expanded the allegedly relevant state of the art to include a "wide spectrum of known and experimental approaches for treatment of gastric acid related diseases" (*see* Ex. 7, Rebuttal report of Johnson, ¶86), not just PPIs.

AstraZeneca never set forth the state of the art regarding proton pump inhibitors (PPIs) or gastric acid inhibitors in its contentions, in anywhere near the depth of the Bartlett and Johnson reports. Rather, AstraZeneca provided only a narrow discussion of the development of (-)-omeprazole salt, as it related to obviousness of its (-)-omeprazole salts. *See, e.g.*, Ex. 31, AstraZeneca's Amended Contentions, pp. 32-36. However, in the Rebuttal Reports of Paul A. Bartlett and Dr. David A. Johnson, AstraZeneca now seeks to interject a much broader theory of the state of prior art, discussing existing proton pump inhibitors and other gastric acid inhibitors, as well as such inhibitors that were under development. *See, e.g.,* Ex. 6, Rebuttal Report of Paul A. Bartlett, filed March 25, 2013, at ¶¶94-113; Ex. 7, Rebuttal Report of David Johnson, ¶¶82-108.

Moreover, against this expanded backdrop, AstraZeneca now seeks to re-characterize the knowledge and considerations of a person of ordinary skill in the art to include this newly introduced spectrum of gastric acid inhibitors. *See, e.g.,* Ex. 6, Rebuttal Report of Paul A. Bartlett, filed March 25, 2013, at ¶¶114-122. Yet, in its contentions, AstraZeneca defined the

knowledge of a person of ordinary skill in the art with reference to only proton pump inhibitors. *See, e.g.*, Ex. 31, AstraZeneca's Amended Infringement Contentions, pg. 22 ("[A] person of ordinary skill involved in PPI drug discovery in May 1993 would select any of the many other known PPIs for research, and would make new structural analogs."). AstraZeneca should not be allowed at this late stage in the case to introduce evidence that entirely alters the landscape of what a person of ordinary skill in the art would have known and considered in developing the claimed (-)-omeprazole salts.

## II. ASTRAZENECA'S ATTEMPT TO INJECT NEW THEORIES VIA EXPERT REPORTS VIOLATES THE COURT'S SCHEDULING ORDER AND APPLICABLE RULES

The Local Patent Rules contemplate that each party be apprised during discovery of the opposing side's contentions with respect to issues in dispute. Accordingly, the Rules expressly require that parties disclose their theories of infringement and invalidity early in litigation. Local Patent Rule 3.6; *King Pharm., Inc. v. Sandoz Inc.*, Case No. 08-5974 (GEB), 2010 WL 2015258, at *4 (D. N.J. May 20, 2010) ("The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed."). The disclosure requirement ensures that "[b]y the time the parties are scheduled to exchange expert reports, they should be acutely aware of the other side's contentions and/or counter contentions." *Sanofi-Aventis v. Barr Labs.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009).

Piecemeal prosecution of a case is fundamentally at odds with the letter and intent of the Rules. Even in cases where a party *does* learn of new information in the course of discovery – unlike the situation here – the party must proceed with diligence in amending its contentions. *O2 Micro Int'l, Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1365-66 (Fed. Cir. 2006).

Parties explicitly are barred from asserting new theories of infringement in expert reports. "Where a party seeks leave to amend its . . . contentions, it must do so 'by order of the Court upon a timely application and showing of good cause.'" *Jazz Pharm., Inc. v. Roxane Labs.*, Case

No. 2:10-CV-06108(ES-CLW), 2012 U.S. Dist. LEXIS 107408, at *6 (D. N.J. July 30, 2012) (quoting L. Pat. R. 3.7). A party cannot bypass this requirement by unilaterally asserting a new theory of infringement, or other new theories, in its expert reports. *Kilopass Tech. Inc. v. Sidense Corp.*, Case No. C 10-02066 SI, 2012 U.S. Dist. LEXIS 115974, at *24 (N.D. Cal Aug. 16, 2012) (rejecting plaintiff's "unilateral" attempt to introduce new theories of infringement in its expert report where "the Patent Local Rules allow amendment of infringement contentions only by order of the Court upon a timely showing of good cause. It is for the Court to make the determination of whether a new theory is consistent with an earlier contention or otherwise appropriate, not the party asserting it.") (internal quotations omitted). AstraZeneca's attempt to unilaterally slip its previously-undisclosed theories into the case is in violation of the Local Patent Rules and the Orders of this Court. *See* L. Pat. R. 3.6 and 3.7, *Jazz Pharm, Inc.*, 2012 U.S. Dist. LEXIS 107408, at *8 (explaining that the Rules are designed to prevent the "shifting sands approach" to a party's contentions).

## III. ASTRAZENECA'S NEW THEORIES UNFAIRLY PREJUDICE HANMI

This case is complicated enough without new theories being injected during expert discovery, and on the eve of trial. Courts have acknowledged that late disclosure prejudices opposing parties whose litigation strategy is based on originally-served infringement contentions. *See Fujitsu Ltd. v. Belkin Int'l, Inc.*, Case No. 10-CV-03972-LHK, at *28-31 (N.D. Cal. Sept. 28, 2012) (defendants would be significantly prejudiced if plaintiff were allowed to proceed with its theories of infringement set forth for the first time in its expert reports); *Jarrow Formulas, Inc. v. Now Health Group, Inc.*, Case No. 10-8301 PSG (JCx) 2012 U.S. Dist. LEXIS 113192, at *47-49 (C.D. Cal. Aug. 2, 2012) (plaintiff's introduction of new theories of infringement through its expert reports was "the very definition of sandbagging.")

Indeed, disclosure of new theories of infringement in expert reports and after the close of fact discovery prevents an opposing party from testing the newly asserted theory through

additional discovery. *Apple, Inc. v. Samsung Electronics Co. Ltd.*, Case No. 11-CV-01846-LHK, 2012 U.S. Dist. LEXIS 108648, at * 26 (N.D. Cal. Aug. 2, 2012) (excluding portions of Samsung's expert reports where "[b]ecause Samsung did not disclose its theories prior to the close of fact discovery, Apple did not have the opportunity to conduct additional fact discovery regarding Samsung's new theories."). Similarly, after the close of fact discovery, experts are "locked-in" to the factual record and cannot test the factual basis of newly asserted theories. *Id.*

Hanmi should have had all or most of the discovery period to consider its responses to AstraZeneca's full case theories, hire experts as appropriate and develop its counter-strategies. Instead, Hanmi is forced to address new issues in a matter of weeks, during a compressed expert discovery and pretrial schedule. While Hanmi has done what it could, there is no cure for the prejudice other than to exclude the belated evidence. Hanmi has been deprived of taking discovery and developing comprehensive rebuttal evidence.

Here, AstraZeneca, in complete disregard of the carefully crafted procedures of the Local Patent Rules and the Court's scheduling orders, and to the severe prejudice of Hanmi, is attempting to interject brand new infringement theories into this case well past the time permitted for such disclosures and other new theories summarized above. In accordance with the governing rules and court precedent, AstraZeneca's untimely theories raised for the first time in its expert reports should be stricken and precluded from being presented at trial.

## IV. CONCLUSION

For the foregoing reasons, Hanmi respectfully requests that its motion be granted. A proposed Order is attached.

Dated: April 29, 2013

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 29, 2013, I caused a copy of the foregoing **Hanmi's Motion *in Limine* No. 1 (To Preclude Testimony of Judi Weissinger and Motion to Strike Weissinger Report)** to be served upon the following counsel by electronic mail:

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